



Clinical trial results:

A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of Nirsevimab, a Monoclonal Antibody With Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm and Term Infants in China

Summary

EudraCT number	2021-005075-38
Trial protocol	Outside EU/EEA
Global end of trial date	24 November 2025

Results information

Result version number	v1 (current)
This version publication date	07 June 2026
First version publication date	07 June 2026

Trial information

Trial identification

Sponsor protocol code	D5290C00006
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05110261
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	Forskargatan 18, Södertälje, Sweden, 151 85
Public contact	Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, information.center@astrazeneca.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 December 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 November 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of nirsevimab in reducing medically attended lower respiratory tract infection (LRTI) due to reverse transcriptase-polymerase chain reaction (RT-PCR)-confirmed respiratory syncytial virus (RSV), compared to placebo, when administered as a single fixed intramuscular (IM) dose to healthy preterm and term infants born ≥ 29 weeks 0 days gestational age (GA) and entering their first RSV season.

Protection of trial subjects:

This study was performed in accordance with the relevant International Council for Harmonisation (ICH) Good Clinical Practice Guidelines - which are based on the ethical principles originating from the Declaration of Helsinki and applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 November 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 800
Worldwide total number of subjects	800
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	44
Newborns (0-27 days)	99
Infants and toddlers (28 days-23 months)	657
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

This Phase 3, randomized, double-blind, placebo-controlled study was conducted at 31 investigational sites in healthy pre-term and term infants born ≥ 29 weeks 0 days GA entering their first RSV season.

Pre-assignment

Screening details:

This study consisted of a screening period (30 days), treatment period (1 day) and a follow-up period (360 days). A total of 800 participants were randomized in a 2:1 ratio to receive either nirsevimab or placebo. As pre-specified in the statistical analysis plan (SAP), results are presented by treatment group.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Nirsevimab

Arm description:

Participants were randomized to receive a single IM dose of nirsevimab 50 milligram (mg) (if weight < 5 kilogram [kg] at time of dosing) or 100 mg (if weight ≥ 5 kg at time of dosing) on Day 1.

Arm type	Experimental
Investigational medicinal product name	Nirsevimab
Investigational medicinal product code	MEDI8897
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Nirsevimab was administered at a dose of 50 mg (if weight < 5 kg at time of dosing) or 100 mg (if weight ≥ 5 kg at time of dosing) on Day 1.

Arm title	Placebo
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Arm description:

Participants were randomized to receive a single IM dose of placebo matched to nirsevimab (0.9% weight/volume [w/v] saline) on Day 1.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo matched to nirsevimab was administered as 0.9% (w/v) saline (sterile for human use) on Day 1.

Number of subjects in period 1	Nirsevimab	Placebo
Started	532	268
Randomized and dosed	521	266
Completed	512	261
Not completed	20	7
Withdrawal by Parent/Guardian	18	7
Unspecified	1	-
Lost to follow-up	1	-

Baseline characteristics

Reporting groups

Reporting group title	Nirsevimab
Reporting group description:	
Participants were randomized to receive a single IM dose of nirsevimab 50 milligram (mg) (if weight <5 kilogram [kg] at time of dosing) or 100 mg (if weight ≥5 kg at time of dosing) on Day 1.	
Reporting group title	Placebo
Reporting group description:	
Participants were randomized to receive a single IM dose of placebo matched to nirsevimab (0.9% weight/volume [w/v] saline) on Day 1.	

Reporting group values	Nirsevimab	Placebo	Total
Number of subjects	532	268	800
Age Categorical			
Units: Participants			
<=3 months	300	150	450
>3 to <=6 months	195	100	295
>6 months	37	18	55
Age Continuous			
Units: months			
arithmetic mean	2.83	2.83	
standard deviation	± 1.905	± 1.858	-
Gender Categorical			
Units: Participants			
Female	269	134	403
Male	263	134	397
Race			
Units: Subjects			
Asian	532	268	800
Ethnicity			
Units: Subjects			
Not Hispanic or Latino	532	268	800

End points

End points reporting groups

Reporting group title	Nirsevimab
Reporting group description: Participants were randomized to receive a single IM dose of nirsevimab 50 milligram (mg) (if weight <5 kilogram [kg] at time of dosing) or 100 mg (if weight ≥5 kg at time of dosing) on Day 1.	
Reporting group title	Placebo
Reporting group description: Participants were randomized to receive a single IM dose of placebo matched to nirsevimab (0.9% weight/volume [w/v] saline) on Day 1.	
Subject analysis set title	Nirsevimab 50 mg
Subject analysis set type	Per protocol
Subject analysis set description: Participants with weight <5 kg at time of dosing received a single IM dose of nirsevimab 50 mg on Day 1.	
Subject analysis set title	Nirsevimab 100 mg
Subject analysis set type	Per protocol
Subject analysis set description: Participants with weight ≥5 kg at time of dosing received a single IM dose of nirsevimab 100 mg on Day 1.	

Primary: Number of Participants With all Medically Attended (MA) Lower Respiratory Tract Infection (Inpatient and Outpatient) due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Through 150 Days After Dosing

End point title	Number of Participants With all Medically Attended (MA) Lower Respiratory Tract Infection (Inpatient and Outpatient) due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Through 150 Days After Dosing
End point description: The determination of all MA RSV LRTI through 150 days post-dose (during a typical 5-month RSV season) was based on the clinical assessment of LRTI by the Investigator and RSV test results obtained from analyzing the respiratory secretions using a validated RSV RT-PCR assay for the detection of RSV performed in a central laboratory. The LRTI events may occur in the inpatient or outpatient visit setting. Intent-to-treat (ITT) population included all randomized participants.	
End point type	Primary
End point timeframe: From dosing (Day 1) to Day 150	

End point values	Nirsevimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	532	268		
Units: participants	9	12		

Statistical analyses

Statistical analysis title	Nirsevimab Versus Placebo
Statistical analysis description: Relative risk reduction of nirsevimab versus placebo, the 95% confidence interval and p-value were estimated based on Poisson regression with robust variance (including stratification factor [age at randomization and GA group] as covariates) obtained from PROC MIANALYZE after missing data imputation.	
Comparison groups	Nirsevimab v Placebo
Number of subjects included in analysis	800
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	Poisson regression with robust variance
Parameter estimate	Relative risk reduction, %
Point estimate	59.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.8
upper limit	82.9

Secondary: Number of Participants With Medically Attended Lower Respiratory Tract Infection (Protocol-Defined, Inpatient and Outpatient) due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Through 150 Days After Dosing

End point title	Number of Participants With Medically Attended Lower Respiratory Tract Infection (Protocol-Defined, Inpatient and Outpatient) due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Through 150 Days After Dosing
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End point description:

Determination of MA RSV LRTI through 150 days post-dose (i.e., typical 5-month RSV season) was based on assessment by Investigator according to protocol definition; RSV test results from analyzing respiratory secretions using validated RSV RT-PCR for detecting RSV in inpatient/outpatient visit. ITT population included all randomized participants.

End point type	Secondary
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End point timeframe:

From dosing (Day 1) to Day 150

End point values	Nirsevimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	532	268		
Units: participants	1	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Hospitalizations due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Lower Respiratory Tract Infection (Protocol-Defined) Through 150 Days After Dosing

End point title	Number of Participants With Hospitalizations due to Reverse Transcriptase-Polymerase Chain Reaction-Confirmed Respiratory Syncytial Virus Lower Respiratory Tract Infection (Protocol-Defined) Through 150 Days After Dosing
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End point description:

RSV hospitalization: respiratory hospitalization with positive RSV test within approximately 2 days of hospital admission (primary) or new onset of respiratory symptoms in already hospitalized participant with objective measure of worsening respiratory status and positive RSV test (nosocomial). ITT population included all randomized participants.

End point type	Secondary
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End point timeframe:

From dosing (Day 1) to Day 150

End point values	Nirsevimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	532	268		
Units: participants	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs), Treatment-Emergent Serious Adverse Events (TESAEs), Treatment-Emergent Adverse Events of Special Interest (TEAESIs), and New Onset Chronic Disease (NOCDs)

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs), Treatment-Emergent Serious Adverse Events (TESAEs), Treatment-Emergent Adverse Events of Special Interest (TEAESIs), and New Onset Chronic Disease (NOCDs)
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End point description:

AE: any untoward medical occurrence in participant/clinical study participant administered study drug and did not necessarily have causal relationship with study drug. SAE: AE that resulted in death, was immediately life-threatening, required inpatient hospitalization/prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was congenital anomaly or birth defect or important medical event that jeopardized participant or required medical treatment. TEAE: AE that occurred on and after administration of study drug through Day 361. AESI: 1 of scientific and medical interest specific to understanding of study drug and required close monitoring and rapid communication by Investigator to Sponsor. NOCD: newly diagnosed medical condition of chronic, ongoing nature, observed after receiving study drug and assessed by Investigator as medically significant. As-treated population: all randomized participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

From first dose of study drug (Day 1) up to end of follow-up period (Day 361)

End point values	Nirsevimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	521	266		
Units: participants				
TEAEs	473	247		
TESAEs	63	47		
TEAESIs	1	0		
NOCDs	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Nirsevimab

End point title	Serum Concentrations of Nirsevimab
End point description:	
Blood samples were collected at specified timepoints to determine the serum concentrations of nirsevimab. The pharmacokinetics (PK) population included all participants who had received any dose of study drug and had at least 1 measurable post-dose serum PK observation and for whom PK blood samples were assumed not to be affected by factors such as important protocol deviations (to be determined prior to unblinding). As pre-specified in the SAP, serum concentrations are presented by weight on study Day 1 (weight <5 kg or ≥5 kg). During the study, participants missed few scheduled site visits for sample collection, and only participants with data collected at specific timepoints are reported. Here, n= number of participants with data collected at the specified timepoints.	
End point type	Secondary
End point timeframe:	
Days 15, 151 and 361	

End point values	Nirsevimab 50 mg	Nirsevimab 100 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	160	311		
Units: microgram per milliliter				
arithmetic mean (standard deviation)				
Day 15 (n=160, 309)	95.232 (± 22.362)	141.240 (± 25.904)		
Day 151 (n=149, 311)	22.802 (± 5.435)	38.395 (± 10.707)		
Day 361 (n=140, 292)	2.886 (± 1.210)	5.117 (± 2.242)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Anti-Drug Antibody (ADA) Against Nirsevimab

End point title	Number of Participants With Anti-Drug Antibody (ADA) Against Nirsevimab
End point description: Blood samples were collected for assessment of ADA against nirsevimab. Treatment-emergent ADA positive was defined as either treatment-induced ADA positive (ADA negative at baseline and post-baseline ADA positive) or treatment-boosted ADA positive (ADA positive at baseline and boosted the pre-existing titre that was boosted to a 4-fold or higher level following study drug administration). Number of participants with treatment-emergent ADA positive sample is presented. As-treated population included all randomized participants who received any amount of study drug. Only participants with data collected are reported	
End point type	Secondary
End point timeframe: From first dose of study drug (Day 1) up to Day 361	

End point values	Nirsevimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	491	254		
Units: participants	48	17		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events and deaths were collected from first dose of study drug (Day 1) up to end of follow-up period (Day 361)

Adverse event reporting additional description:

As-treated population included all randomized participants who received any amount of study drug. As pre-specified in SAP, results are presented by treatment group.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants were randomized to receive a single IM dose of placebo matched to nirsevimab (0.9% [w/v] saline) on Day 1.

Reporting group title	Nirsevimab
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Reporting group description:

Participants were randomized to receive a single IM dose of nirsevimab 50 mg (if weight <5 kg at time of dosing) or 100 mg (if weight ≥5 kg at time of dosing) on Day 1.

Serious adverse events	Placebo	Nirsevimab	
Total subjects affected by serious adverse events			
subjects affected / exposed	47 / 266 (17.67%)	63 / 521 (12.09%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of skin			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal neoplasm benign			

subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular yolk sac tumour			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Scalp haematoma			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kawasaki's disease			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Foreign body in respiratory tract			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			

subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cerebral palsy			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital arterial malformation			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptorchism			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-compaction cardiomyopathy			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 266 (0.00%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tethered cord syndrome			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 266 (0.00%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infantile diarrhoea			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 266 (0.38%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Tenosynovitis stenosans			

subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 266 (0.75%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 266 (0.75%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	1 / 266 (0.38%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	4 / 266 (1.50%)	9 / 521 (1.73%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus pneumonia			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			

subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exanthema subitum			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes pharyngitis			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpangina			
subjects affected / exposed	3 / 266 (1.13%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			

subjects affected / exposed	1 / 266 (0.38%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Omphalitis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia moraxella			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	2 / 266 (0.75%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	19 / 266 (7.14%)	17 / 521 (3.26%)	
occurrences causally related to treatment / all	0 / 22	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	2 / 266 (0.75%)	3 / 521 (0.58%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 266 (0.00%)	2 / 521 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 266 (0.38%)	3 / 521 (0.58%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	3 / 266 (1.13%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis bacterial			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 266 (0.38%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			

subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 266 (0.38%)	0 / 521 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 266 (0.38%)	3 / 521 (0.58%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Poor feeding infant			
subjects affected / exposed	0 / 266 (0.00%)	1 / 521 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	Nirsevimab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	222 / 266 (83.46%)	436 / 521 (83.69%)	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 266 (5.26%)	21 / 521 (4.03%)	
occurrences (all)	15	22	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	55 / 266 (20.68%)	94 / 521 (18.04%)	
occurrences (all)	66	111	

Gastrointestinal disorders	Functional gastrointestinal disorder			
	subjects affected / exposed	17 / 266 (6.39%)	35 / 521 (6.72%)	
	occurrences (all)	22	42	
	Dyspepsia			
	subjects affected / exposed	24 / 266 (9.02%)	31 / 521 (5.95%)	
	occurrences (all)	31	37	
	Diarrhoea			
	subjects affected / exposed	25 / 266 (9.40%)	55 / 521 (10.56%)	
	occurrences (all)	28	63	
Skin and subcutaneous tissue disorders				
	Eczema			
	subjects affected / exposed	29 / 266 (10.90%)	74 / 521 (14.20%)	
	occurrences (all)	38	81	
Infections and infestations				
	Upper respiratory tract infection			
	subjects affected / exposed	174 / 266 (65.41%)	349 / 521 (66.99%)	
	occurrences (all)	348	744	
	Pneumonia			
	subjects affected / exposed	12 / 266 (4.51%)	27 / 521 (5.18%)	
	occurrences (all)	12	30	
	Bronchitis			
	subjects affected / exposed	57 / 266 (21.43%)	89 / 521 (17.08%)	
	occurrences (all)	77	112	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 April 2021	The purpose of this amendment was: To remove the PK parameter estimations because there were few blood samplings points. It was expected that there would be not enough data for non-compartmental analysis. To further reduce the volume of blood collection and to combine 2.5-5 kg and >5 kg due to limited number of infants >5 kg at birth.
01 June 2023	The purpose of this amendment was: To add the estimands to give a precise description of the treatment effect reflecting the clinical question posed by the objectives, to remove the description which was not implemented in the study execution. To clarify the detail of statistical hypotheses, the efficacy analysis methods of primary and secondary endpoints analysis, and detail of survival analysis. To focus healthcare resource utilisation summaries on the most important aspects of magnitude and the most important efficacy events, especially given the impact on the event numbers from Coronavirus disease-2019 pandemic and to optimise PK/pharmacodynamic samples collect process to avoid duplicated sample collection.
04 August 2025	The purpose of this amendment was to modify the primary endpoint to all MA RSV LRTI and retain the original primary endpoint as a secondary endpoint, to provide the primary analysis after all participants completed the last visit of the study, to update the sample size justification based on the modified endpoints, to make changes to align with the updated efficacy endpoints and with the summary analyses employed for the secondary endpoints, to remove the secondary estimand details, to add rationale per the requirements of the template, to employ a summary of the incidence of the events for all the secondary efficacy endpoints, to add missing words to ensure that the definition and criteria of objectives were complete, to distinguish the concept of 'all medically attended LRTI' from 'the protocol-defined LRTI' and to align with the updated primary endpoint, to improve clarity of the description and to keep consistent with the endpoints and their analysis methods, to be consistent with the analysis methods in Global Study MELODY (D5290C00004 [2019-000114-11]) and to clarify that per-protocol analysis would not be conducted based on the guidance of International Council for Harmonisation (ICH) E9 addendum.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported